

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
14 August 2003 (14.08.2003)

PCT

(10) International Publication Number  
**WO 03/065911 A1**

(51) International Patent Classification<sup>7</sup>: **A61B 17/64**

David [US/US]; 3556 Rock Garden Cove, Bartlett, TN 38135 (US). AUSTIN, Ed [US/US]; 8015 Steven Franklin, Bartlett, TN 38133 (US). NELSON, Kenneth [US/US]; 600 Monteigne Blvd., Memphis, TN 38103 (US). GRUSIN, Kelley [US/US]; 1999 Brantwood Cove, Germantown, TN 38139 (US).

(21) International Application Number: **PCT/US03/02712**

(74) Agent: PRATT, John, S.; Kilpatrick Stockton LLP, 1100 Peachtree Street, Suite 2800, Atlanta, GA 30309-4530 (US).

(22) International Filing Date: 30 January 2003 (30.01.2003)

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

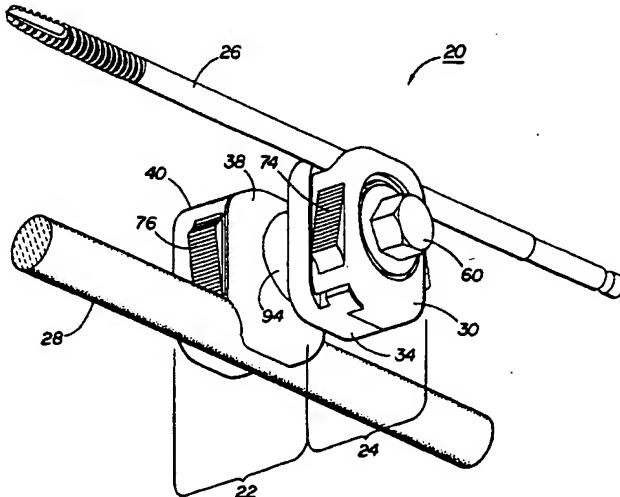
(25) Filing Language: English

(26) Publication Language: English

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,

[Continued on next page]

(54) Title: EXTERNAL FIXATION SYSTEM



**WO 03/065911 A1**

(57) Abstract: An external fixation system having a fixation component (20) comprising: a) a first capture member (24) adapted to capture a second element (26) of an orthopedic fixation system; and b) a second capture member (22) adapted to capture a second element (28) of an orthopedic fixation system and coupled to the first capture member such that the coupling (86,94,110) allows the first capture member and the second capture member to rotate about three axes relative to each other element and move along that axis; wherein the coupling is adapted to secure the first and the second capture members from rotation with an activation (100); and wherein the second capture member is adapted to capture the second element by snapping onto the second element from substantially perpendicular to longitudinal axis of the second element.

WO 03/065911 A1



ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI,  
SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN,  
GQ, GW, ML, MR, NE, SN, TD, TG).

— before the expiration of the time limit for amending the  
claims and to be republished in the event of receipt of  
amendments

**Declaration under Rule 4.17:**

— of inventorship (Rule 4.17(iv)) for US only

**Published:**

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

EXTERNAL FIXATION SYSTEM

This application claims priority to U.S. Application No. 10/067,052, filed February 4, 2002, now pending, entitled "External Fixation System," the entire contents of which are hereby incorporated by reference.

5

Field of the Invention

This invention relates generally to methods, systems, and devices for orthopedic external fixation and more particularly to an external fixation system having an improved fixation component for constructing a stable, adjustable fixation system that cooperates with other systems, and methods of use thereof.

10

Background of the Invention

Surgeons use external fixation systems regularly to treat certain bony skeletal injuries or conditions, such as acute fractures of the skeleton, soft tissue injuries, 15 delayed union of the skeleton when bones are slow to heal, nonunion of the skeleton when bones have not healed, malunion of broken or fractured bones, congenital deformities resulting in malposition of bone, and bone lengthening, widening, or twisting. Treatment of these conditions often includes stabilization and reduction using an external fixation system. These systems may include a frame comprised of 20 one or more of fixation components and one or more fixation elements. As used herein, fixation component refers to a device for positioning one or more parts of an external fixation system, and fixation element refers to one or more of a bar, rod, wire, or pin used in an external fixation system. Wires may be threaded, beaded, or smooth, and pins may be threaded or smooth. Generally, one or more bone pins or 25 wires are inserted into the tissue and bone and then the remainder of the fixation system is assembled. It is often important that a surgeon is able to place the external fixation system on the patient and then reduce the fracture in an expedited manner. Fracture patterns are infinite and may require the fixation system to move in multiple planes simultaneously in order to stabilize and reduce the fracture properly.

30

Current external fixation system designs vary, but generally include a mechanism for attaching at least one fixation element to a fixation component to form a construct, or frame, to support a fracture. In general, at least one pin or wire is drilled into the bone. Bone pins typically have one end that is either or both self-

drilling and self-tapping, and have a diameter sufficient to resist bending. Bone wires are generally smaller in diameter. Bone pins or wires may be drilled completely through the bone, exiting the skin on the opposite side of the bone, called "transfixation pins," or may extend through the bony skeleton and out only one side 5 of the limb, called "half pins." Current fixation components generally either connect a bar to a bar, a bar to a wire, or a bar to a pin. The frame of an external fixation system may include unilateral bars, which extend along the side of a patient's body, or circumferential or half rings, which encircle a patient's body member entirely or in part. Systems designed to use a circumferential ring or half ring include the 10 ILIZAROV™ brand system and the SPATIAL FRAME™ brand system. The SPATIAL FRAME™ brand system is described in U.S. Patent No. 5,702,389, which is hereby incorporated by reference. Generally, circumferential and half rings have a rectangular cross-section.

When stabilizing and reducing a fracture using an external fixation system, it 15 is important to properly align the bone fragments. Such alignment requires a fixation component that securely joins the pins and wires to the bars, but that is readily adjustable. In many cases, two pins are inserted below the fracture and two pins are inserted above the fracture. The surgeon then attaches a fixation component to each pin, bridging the fixation components together with rods, or bars. These bars form the 20 frame of the external fixation system. As additional fixation components are added to the system in different planes, the frame becomes less adjustable. Current fixation systems permit a surgeon to choose the positioning of only two fixation components because after placement of two components, additional fixation components will only fit into set positions. During a procedure, it is often necessary to further reduce a 25 fracture, which requires removal of the bars (and loss of positioning) and then replacement of the bars in the frame. Thus, additional reduction is difficult to achieve and requires reestablishment of optimal position. Current systems are also highly dependent on accurate pin or wire placement. For example, if the pins or wires are angled incorrectly, the frame cannot be properly constructed.

30 One current external fixation component design includes two clamps that rotate in one plane to allow limited manipulation of the external fixation component. One jaw of each clamp of this design includes a toothed chip mechanism that has a surface with teeth similar to a poker chip. The teeth mate and lock when compressed,

- and thereby resist rotation in one plane after the clamps are in place. This poker chip design requires that the two fixation elements retained by the component are parallel to each other in at least one plane that is parallel to the poker chip surface, so that the angular relationship between the two fixation elements is always zero in that plane.
- 5     Therefore, this system requires a parallel plane between the pin or wire and bar (or between two bars) for each fixation component. This requirement limits the system, as the positioning of each clamp is inhibited. Similar to other current designs, this design becomes substandard when several fixation components are used because it becomes constrained.
- 10    In addition, the clamps of many current designs are adjacent a central shaft and are both locked upon tightening of a single screw, further constraining the system. Many current designs also allow for placement of the pins in the pin clamp of a fixation element only from the side and require a bent bar for placement of the system proximate the patient, if it is necessary to conform the system to the patient's anatomy. In addition, current designs use compression to hold the bar or pin in place, and may allow dislodgement of the pin or bar upon application of a great amount of pressure to the system when being placed.
- 15    Other prior art designs include circumferential rings or half rings, such as those in the ILIZAROV™ and SPATIAL FRAME™ brand systems. These specialized systems are often used for reduction of a fracture of the proximal tibia or distal femur. Generally, wires connected to half rings are used to stabilize a fracture. These specialized systems do not cooperate with general external fixation systems, and must be used separately.
- 20    Thus, there is a need for an external fixation system that provides a greater degree of freedom of rotation of the fixation components and therefore a more flexible frame construct, sequential locking of capture members, allowing greater adjustability, and cooperation with specialized fixation systems.

#### Summary of the Invention

- 25    An external fixation system according to one embodiment of this invention allows manipulation of an external fixation component in any plane independent of the number of fixation components used, which is provided by the ability of the fixation component to rotate in multiple planes. Further, an improved fixation

component according to one embodiment of this invention provides an external fixation system that does not bind or become constricted when numerous fixation components are used, providing the surgeon a stable system that is adjustable.

- One embodiment of a fixation component according to this invention includes
- 5 two capture members, a first capture member adapted to capture a first fixation element and a second capture member adapted to capture a second fixation element. The capture members are coupled such that the coupling allows the first capture member and second capture member to rotate about three axes relative to each other and the second capture member to rotate about one axis of the second fixation element
  - 10 and move along that axis. The coupling is adapted to secure the first and second capture members from rotation and secure the second capture member from rotating about and moving along the axis of the second fixation element with a single activation. The second capture member is adapted to capture the second fixation element by snapping onto the second element from substantially perpendicular to the
  - 15 longitudinal axis of the second element.

One feature of one embodiment of this invention is a fixation component that provides a greater degree of freedom of rotation.

- Another feature of one embodiment of this invention is a fixation component that simultaneously locks a capture member to a fixation element and locks the joint
- 20 between two capture members.

- Another feature of one embodiment of this invention is a modular design whereby at least one of the two capture members of a fixation component may be interchangeable with another capture member. For example, if a fixation component has two capture members each for receiving a bar, the two capture members may be
- 25 separated at the joint, and another capture member, for receiving a pin, may be attached to one of the original two capture members to form a fixation component with one capture member for receiving a bar and the other capture member for receiving a pin.

- Yet another feature is a fixation component that allows one capture member to
- 30 be locked to retain a fixation element without forcing the second capture member also to be locked, allowing additional adjustment of position of the second capture member.

Another feature of one embodiment according to this invention is a fixation component having a locking mechanism that is not dislodged by application pressure.

Yet another feature of one embodiment of this invention is a fixation component that cooperates with specialized fixation systems.

5        According to the present invention there is provided an external fixation component comprising (a) a first capture member adapted to capture a first element of an orthopedic fixation system; and (b) a second capture member adapted to capture a second element of an orthopedic fixation system and coupled to the first capture member such that the coupling allows the first capture member and the second  
10      capture member to rotate about three axes relative to each other and the second capture member to rotate about one axis of the second element and move along that axis; wherein the coupling is adapted to secure the first and second capture members from rotation with an activation; and wherein the second capture member is adapted to capture the second element by snapping onto the second element from substantially  
15      perpendicular to the longitudinal axis of the second element.

According to the present invention there is provided a method of treating a skeletal condition or injury using an external fixation system, the method comprising:  
20      (a) inserting a first fixation element into a bone; (b) capturing the first fixation element in a first fixation component by snapping onto the first fixation element from substantially perpendicular to the longitudinal axis of the first fixation element, the first fixation component comprising: (i) a first capture member adapted to capture an element of an orthopedic fixation system; and (ii) a second capture member adapted to capture an element of an orthopedic fixation system and coupled to the first capture member such that the coupling allows the first capture member and the second  
25      capture member to rotate about three axes relative to each other; wherein the coupling is adapted to secure the first and second capture members from rotation with a single activation; (c) capturing a second fixation element in the first fixation component by snapping onto the second fixation element from substantially perpendicular to the longitudinal axis of the second fixation element; and (d) engaging the single  
30      activation to secure the first and second capture members from rotation.

Brief Description Of The Drawings

Figure 1 is a perspective view of a fixation component according to one embodiment of this invention.

5       Figure 2 is an exploded perspective view of the fixation component of Figure 1:

Figure 3 is a perspective view of the fixation component of Figure 1 with a pin and bar inserted.

10      Figure 4 is a cross-sectional view of the fixation component taken along lines 4-4 in Figure 1.

Figure 5 is a cross-sectional view of the fixation component taken along lines 5-5 in Figure 1.

Figure 6 is an exploded perspective view of the second capture member of Figure 1.

15      Figure 7 is a perspective view of a fixation component according to an alternative embodiment of this invention.

Figure 8 is an exploded perspective view of the fixation component of Figure 7.

20      Figure 9 is a perspective view of the fixation component of Figure 7, with bars inserted in the capture members.

Figure 10 is a perspective view of a fixation component according to an alternative embodiment of this invention.

10      Figure 11 is an exploded perspective view of the fixation component of Figure 10.

25      Figure 12 is a perspective view of an external fixation system according to one embodiment of this invention.

Figure 13 is an enlarged fragmentary perspective view of selected fixation components of Figure 12.

30      Figure 14 is an exploded perspective view of an alternative embodiment of this invention.

Figure 15 is a plan view of the fixation component of Figure 14.

Figure 16 is a cross-sectional view of the fixation component of Figure 14 taken along lines 16-16 of Figure 15.

Figure 17 is an exploded perspective view of an alternative embodiment of this invention.

Figure 18 is a plan view of the fixation component of Figure 17.

Figure 19 is a cross-sectional view of the fixation component of Figure 17  
5 taken along lines 19-19 of Figure 18.

#### Detailed Description of the Invention

Methods, systems, and devices according to this invention seek to provide improved external fixation, including an improved fixation component allowing an 10 increase in freedom of rotation, independent locking of capture members, a more stable, yet more flexible frame, and cooperation with specialized fixation systems. External fixation systems according to embodiments of this invention may include fixation components designed to retain one or more fixation elements. In general, the fixation components either connect a bar to a bar; a bar to a pin; a bar to a wire; or a 15 bar to a circumferential or half ring. Each fixation component generally includes two capture members, and each capture member includes a base and a head.

One embodiment of a fixation component according to this invention includes a first capture member and a second capture member connected by a joint. Each capture member includes a channel, which allows attachment of a fixation element 20 from the side. Prior to being locked down, each fixation element can slide (back and forth) and rotate within the channel providing two degrees of freedom between the fixation element and the capture member. The first and second capture members are connected by a joint that allows each capture member to rotate with respect to the other capture member. The joint also allows rotation of up to 50° in any plane (25° 25 each way), increasing the degree of freedom of rotation. In one embodiment, angulation is limited to 50° due to profile height constraints. However, in another embodiment more angulation may be provided. Thus, each capture member is provided three degrees of rotational freedom relative to the other capture member. An external fixation system including fixation components according to this invention 30 allows movement of the bone along six separate axes, a combination of three orthogonal translational axes and three orthogonal rotational axes.

In one embodiment according to this invention, a fixation component having a unique joint allows simultaneous locking of one capture member and the joint. In

addition, one capture member may be locked in place while the second capture member continues to freely rotate. In this manner, the surgeon is able to lock one capture member and continue to rotate the second capture member for final positioning. The surgeon is also able to loosen only one capture member to gain 5 additional reduction, if required, without losing placement, as occurs with current systems when additional reduction is required.

Consider one example of systems and devices according to this invention. As shown in Figures 1-6, a bar-to-pin fixation component 20 includes a first capture member 24 and a second capture member 22. First capture member 24 retains a pin 26, while second capture member 22 is configured to retain a bar 28, as shown in 10 Figure 3. A base 30 of first capture member 24 includes a groove 32, while a head 34 of first capture member 24 contains a wedge 36, which together are adapted to retain pin 26. Likewise, a base 38 and a head 40 of second capture member 22 include a groove 42 and a wedge 44, together adapted to retain bar 28. In one embodiment, 15 groove 42 of second capture member 22 has splines 46, which provide rotational stability of bar 28 and penetrate the surface of bar 28 when second capture member 22 is tightened. Alternatively, the second capture member may be adapted to retain a pin and the first capture member may be adapted to retain a bar. In an alternative embodiment, both the first and second capture members are configured to retain a bar, 20 as shown in Figures 7-9. In another embodiment, one capture member is adapted to retain a wire, while the other capture member is adapted to retain a bar. In another embodiment, the capture members are modular allowing for each capture member to be connected to a similarly designed capture member. Additional embodiments are further described below.

As shown in Figure 2, head 34 of first capture member 24 has a recess 48 25 adapted to receive a spring 50, while base 30 of first capture member 24 includes a stop 52. A first track 54 on each side of head 34 slides in a second track 56 on each side of base 30, allowing head 34 and base 30 of first capture member 24 to translate with respect to each other. In an alternative embodiment, second track 56 slides in 30 first track 54. In one embodiment, one of first and second tracks 54, 56 is an L-shaped track, while the other track is shaped to receive the L-shaped track. As a force in a direction perpendicular to the pin is exerted against groove 32 and wedge 36 of first capture member 24, head 34 moves, compressing spring 50 against the extended

portion of base 30. Spring 50 compresses until it exerts a force in a direction perpendicular to pin 26 that is equal and opposite to the force exerted against wedge 36. At that point, head 34 stops moving and holds pin 26 in groove 32 and wedge 36, which together form channel 58.

5       The angular position of channel 58 is set by tightening a first fastener 60. Prior to tightening of first fastener 60, the cartridge mechanism, in the loosened state, does not allow pin 26 to passively separate or detach from capture member 24. Base 30 of first capture member 24 includes an elevated portion 61, as shown in Figure 4, forcing two points of contact between base 30 and head 34 in order to increase the  
10 holding power of first capture member 24. Base 38 of second capture member 22 also includes an elevated portion 63, also shown in Figure 4, which increases the holding power of second capture member 22 in the same manner.

Second capture member 22 also includes a cartridge mechanism for retaining bar 28. Head 40 of second capture member 22 has a recess 62 adapted to receive a  
15 spring 64, while base 38 of second capture member 22 includes a stop 66. A first track 68 on each side of head 40 slides in a second track 70 on each side of base 38. In an alternative embodiment, second track 70 slides in first track 68. In one embodiment, one of first and second tracks 68, 70 is an L-shaped track, while the other track is shaped to receive the L-shaped track. Groove 42 and wedge 44 of  
20 second capture member form a second capture member channel 72, which receives a bar 28. Bar 28 is retained in second capture member 22 in the same manner as first capture member 24 retains pin 26.

In an alternative embodiment, one or both capture members may include two recesses for receiving two springs and two spring stops. In the embodiments shown,  
25 the recess, spring, and stop are located on one side of the capture member. In an alternative embodiment, the recess, spring, and spring stop are in the middle of the capture member, or are on the other side of the capture member. In one embodiment, heads 40 and 34 of capture members 22 and 24, respectively, include grip surfaces 74 and 76 for gripping and sliding heads 40 and 34 in relation to bases 38 and 30, respectively. In one embodiment, grip surfaces 74 and 76 include ridges.

A threaded end 78 of first fastener 60 is adjacent a biasing element, such as a center spring 80, and passes through a keyhole aperture 82 in head 34 of first capture member 24, mating to internal threads 84 in base 30 of first capture member 24.

Keyhole aperture 82 of head 34 if first capture member 24 allows a reduced diameter neck 85 of first fastener 60 to translate within the aperture 82. Tightening of first fastener 60 locks first capture member 24 and rigidly retains pin 26. In an alternative embodiment, aperture 82 is circular, or any other suitable shape.

5        A connector 86 having an end 88 and a shaft 90 extends through a keyhole aperture 92 in base 30 of first capture member 24. In one embodiment, connector 86 is a ball stud, as shown in Figure 2, having a spherical end. End 88 of connector 86 is received in a planetary member 94 of base 30 of first capture member 24. As used herein, a planetary member refers to an object that is received in another object, and  
10      that receives another object within itself. In one embodiment, planetary member 94 is an outer sphere, as shown in the figures. Shaft 90 of connector 86 extends through an aperture 96 in base 38 of second capture member 22 and an aperture 98 in head 40 of second capture member 22, and mates with a second fastener 100. Threads 102 on shaft 90 of connector 86 mate with internal threads 104 of second fastener 100.

15        A slot 106 in aperture 96 of base 38 of second capture member 22 is adapted to receive a key 108 on shaft 90 of connector 86. Key 108 and slot 106 thus prevent rotation of connector 86 within second capture member 22. In another embodiment, any suitable mechanism for preventing rotation of the connector is used. In other words, the connector fits through the base of the first capture member and the end is  
20      received in the planetary member of the base, while the shaft of the connector extends through both the base and head of the second capture member and threads to a second fastener. A planetary member, for example outer sphere 94, fits within a cooperating surface 110, which is machined into the one side of base 38 of second capture member 22. Tightening of second fastener 100 on second capture member 22 draws  
25      connector 86 into planetary member 94, locking the second capture member and the joint to make it rigid. In one embodiment, one or both of the planetary member and cooperating surface may be tapered. For example, a taper of 10°, 15°, 20°, or 30° may be used on each.

30        The joint mechanism described above allows the second capture member to rotate with respect to the planetary member of the first capture member, and allows the first capture member to grasp and lock a pin while permitting the second capture member to continue to rotate. Independent tightening of the capture members provides the surgeon flexibility to snap a fixation element to a capture member and

then to manipulate the second capture member before locking the second capture member in order to achieve a more stable frame. In this manner, independent tightening of each capture member of the external fixation component allows more precise angular positioning. Alternative embodiments of a joint mechanism between 5 two capture members are described below with reference to Figures 14-19.

Other embodiments, such as a bar-to-bar fixation component, shown in Figures 7-9, and a bar-to-wire fixation component, also may contribute to a more stable, more adjustable external fixation system. These embodiments function similarly to the bar-to-pin fixation component, with the capture members having a 10 wedge and groove adapted to form a channel sized for receiving either a bar or a wire, depending on the component.

In one embodiment, a cartridge locking of the pin and bar is provided, as described above. However, in alternative embodiments, other one-piece designs may be used. For example, a solid piece of aluminum metal having the shape of the two 15 part head and base cartridge construct of the two capture members may be used. This one-piece design includes a channel in each one piece capture member and a slot that extends close to the rear portion of the capture member. The slot causes the material to behave similar to a spring and allows the capture member to open when pressure is placed against it, so that a fixation element may be snapped into place in the channel.

Several mechanisms may be used to improve the locking capabilities of the joint. Coatings or elastic materials or alternate taper shapes may be applied to any of 20 the articulating surfaces. For example, coatings or elastic materials or alternate taper shapes may be applied to one or both of the planetary member and cooperating surface so that a textured surface on either or both improves locking. In one 25 embodiment, the cooperating surface is coated with SC729, a coating manufactured by Hitemco. In this embodiment, the cooperating surface is very rough and is made from tungsten cobalt carbide. In this embodiment, the value for slip increases to about 240 in.-lb., from about 140 in.-lb. without the coating. In an alternative embodiment, a mechanical locking pattern is applied. For example, splines and 30 dimples may be added to one or both of planetary member and cooperating surface, providing teeth to grab when locking, thereby improving the locking function. A 30 degree chosen taper configuration on the inside of the planetary member mating surface uses a taper design to achieve torque strength of up to 200 in.-lb.

In an alternative embodiment, a fixation component is designed for attachment to a circumferential external fixator system, such as an ILIZAROV™ brand system, a SPATIAL FRAME™ brand system, or other spatial frame, to achieve a hybrid external construct. In this embodiment, shown in Figures 10-11, the fixation  
5 component includes a capture member for retaining a bar and a capture member for retaining a half or circumferential ring having a generally rectangular cross-section. Use of a fixation component having a capture member for retaining a ring allows a surgeon to create a hybrid frame, using both a standard external fixation system and a system that includes a circumferential external frame. This hybrid system is very  
10 useful in adapting a system for treating a shaft fracture, or typical in-line fracture, to one for treating a plateau fracture, which is a fracture in a joint space.

Referring to Figures 10 and 11, a T-component 112 according to one embodiment of a fixation component of this invention includes a second capture member 114 that is similar to the second capture member described above with  
15 respect to the bar-to-pin fixation component. A head 116 of second capture member 114 has a recess 118 adapted to receive a spring 120, while a base 122 of second capture member 114 includes a stop 124. Recess 118 and spring 120 function as described above. Second capture member 114 also includes a first track 126 and a second track 128 so that head 116 and base 122 translate and retain a bar in a groove  
20 130 and a wedge 132 in the same manner as described above.

Base 122 of second capture member 114 also includes a cooperating surface 134, which is adapted to receive a planetary member 136 of a first capture member 156. A connector 138, which, as described above and shown in Figure 11, may be a ball stud, has a shaft 140 that extends through apertures 142 and 144 in base 122 and  
25 head 116, respectively, of second capture member 114. A slot 146 in aperture 142 of base 122 is adapted to receive a key 148 on shaft 140 of connector 138 in order to prevent rotation of connector 138 within second capture member 114. Threads 150 on shaft 140 mate with a second fastener 152, while an end 154 is received in planetary member 136.

30 First capture member 156 includes a base 158 and a head 160, each having a recess 162 and 164, respectively, that together form a channel 166, adapted to receive a ring having a rectangular cross-section. Head 160 has an extension 168 that fits into a rim 170 of base 162. A rod 172 includes second threads 174 that mate with internal

threads 176 of an aperture 178 of base 158 after extending through an aperture 180 of head 160. A biasing element 182, such as a spring, passes over rod 172 and also into an aperture 184 of a first fastener 186. First threads 188 of rod 172 mate with internal threads 190 of first fastener 186. Tightening of first fastener 186 thus locks base 158 and head 160 of first capture member 156. Second capture member 114 is free to rotate about planetary member 136 of base 158 of first capture member 156 until second fastener 152 is tightened, at which time both second capture member 114 and planetary member 136 and cooperating surface 134, which form the joint, are locked.

In an alternative embodiment, other locking mechanisms may be used, such as a universal joint mechanism, which allows independent movement in different directions. In yet another alternative embodiment, the capture member may include a flip through for the bar or pin, rather than a snap-on from the side as described above.

One embodiment of a fixation component of this invention is made from titanium and aluminum. In this embodiment, the heads of the capture members are made from aluminum and the remaining parts from titanium. In alternative embodiments, fixation components are made from metals, alloys, plastics, composites, ceramics, or any other suitable material.

As noted above, additional alternative embodiments of capture members and a joint mechanism between two capture members are shown in Figures 14-19. One alternative joint mechanism is shown in Figures 14-16, while another alternative is shown in Figures 17-19. The capture members shown in Figures 14-19 generally perform in a similar manner as the capture members described above with regard to the receipt of fixation elements and engagement of the base and head of each capture member.

As shown in Figures 14-16, a fixation component 200 includes a first capture member 202 and a second capture member 230. Capture members 202 and 230 may be designed to retain one of any of a pin, wire, bar, at least a partial ring, or other fixation element. As shown in Figures 14-16, each capture member is designed to receive a bar. A base 204 of first capture member 202 includes a groove 206, while a head 208 of first capture member 202 contains a wedge 210, which together are adapted to retain a fixation element. Likewise, a base 232 and a head 234 of second capture member 230 include a groove 236 and a wedge 238, together adapted to retain a fixation element in the same manner as described above.

- Head 208 of first capture member 202 has a recess (not shown) adapted to receive a spring 214, while base 204 of first capture member 202 includes a stop 216. The recess, spring 214, and stop 216 function in the same manner as described above. First capture member 202 also includes a first track 218 and a second track 220 so that
- 5 head 208 and base 204 translate and retain a fixation element in a channel 222 formed by groove 206 and wedge 210 in the same manner as described above. The angular position of channel 222 is set by tightening a first fastener 224. Prior to tightening of first fastener 224, the cartridge mechanism, in the loosened state, does not allow an inserted fixation element to passively separate or detach from capture member 202.
- 10 Second capture member 230 also includes a cartridge mechanism for retaining a fixation element. Head 234 of second capture member 230 has a recess 240 adapted to receive a spring 242, while base 232 of second capture member 230 includes a stop 244. Second capture member 230 also includes a first track 246 and a second track 248 so that head 234 and base 232 translate and retain a fixation element in a channel
- 15 250 formed by groove 236 and wedge 238 in the same manner as described above. The angular position of channel 250 is set by tightening a second fastener 252. Prior to tightening of second fastener 252, the cartridge mechanism, in the loosened state, does not allow an inserted fixation element to passively separate or detach from capture member 230.
- 20 In the embodiments shown, the recess, spring, and stop are located on one side of the capture member. In an alternative embodiment, the recess, spring, and spring stop are in the middle of the capture member, or are on the other side of the capture member. In one embodiment, heads 208 and 234 of capture members 202 and 230, respectively, include grip surfaces 226 and 254 for gripping and sliding heads 208 and
- 25 234 in relation to bases 204 and 232, respectively. In one embodiment, grip surfaces 226 and 254 include ridges.

A threaded end 256 of second fastener 252 passes through an aperture 258 in head 234 of second capture member 230, mating to internal threads 260 in base 232 of second capture member 230. Tightening of second fastener 252 locks second capture member 230 and rigidly retains an inserted fixation element.

A connector 270 having an end 272 and a shaft 274 extends through bore 276 in base 204 of first capture member 202. In one embodiment, connector 270 is a ball stud, as shown in Figure 14, having a spherical end. End 272 of connector 270 is

received in a spherical collet 278 of base 204 of first capture member 202. Shaft 274 of connector 270 extends through bore 276 in base 204 of first capture member 202 and an aperture 280 in head 208 of first capture member 202, and mates with first fastener 224. Threads 282 on shaft 274 of connector 270 mate with internal threads 5 228 of first fastener 224. A slot 284 in bore 276 of base 204 of first capture member 202 is adapted to receive a key 286 on shaft 274 of connector 270. Key 286 and slot 284 thus prevent rotation of connector 270 within first capture member 202.

The end of bore 276 may be tapered or countersunk. When connector 270 is inserted through the countersunk end of bore 276 and aperture 280 of head 208 of first 10 capture member 202, end 272 rests against the countersunk end of bore 276. First fastener 224 is threaded onto shaft 274 so that as first fastener 224 is tightened against capture member 202, end 272 is pulled through base 204 and head 208 of capture member 202, forcing spherical collet 278 to expand.

A spherical pocket 290 of base 232 of second capture member 230 receives 15 spherical collet 278. In a loosened state (i.e., first fastener 224 is not fully tightened and spherical collet 278 is not fully expanded), spherical collet 278 may be retained within spherical pocket 290, and spherical collet 278 may or may not be biased against spherical pocket 290 to provide resistance for the joint mechanism. When end 272 of connector 270 is not expanding spherical collet 278, capture members 202 and 20 230 may be rotated about or detached from each other. When first fastener 224 is tightened and spherical collet 278 fully expanded, capture members 202 and 230 cannot be rotated about each other or detached from each other. The tightening of first fastener 224 locks first capture member 202 and the joint to make it rigid. In one embodiment, one or both of the spherical collet and spherical pocket may be tapered. 25 For example, a taper of 10°, 15°, 20°, or 30° may be used on each. Several mechanisms may be used to improve the locking capabilities of the joint, including coatings, elastic materials, or alternate taper shapes as discussed above.

The joint mechanism shown in Figures 14-16 allows the first capture member to rotate with respect to the spherical pocket of the second capture member, and 30 allows the second capture member to grasp and lock a fixation element while permitting the first capture member to continue to rotate. Independent tightening of the capture members provides the surgeon flexibility to snap a fixation element to a capture member and then to manipulate the first capture member before locking the

first capture member in order to achieve a more stable frame. In this manner, independent tightening of each capture member of the external fixation component allows more precise angular positioning.

In addition to increasing the degrees of freedom of movement of fixation components and allowing for more precise angular positioning, the use of the joint mechanism shown in Figures 14-16 provides a modular external fixation system for use by surgeons. Rather than providing pre-assembled fixation components in a surgical tray, separate capture members, not yet attached to other capture members to form fixation components, may be provided. For example, instead of providing a predetermined number of bar-to-bar fixation components and bar-to-pin fixation components in a surgical tray, a system may include a specified number of capture members for receiving bars and capture members for receiving pins. The capture members may be connected by the surgeon, or an assistant, using the joint mechanism shown in Figures 14-16 to form specific fixation components (e.g., bar-to-bar, bar-to-pin, bar-to-wire, etc.) as desired based upon the surgery being performed. This provides better inventory control and should reduce the number of capture members and/or fixation components required to be provided in a surgical tray.

Another alternative embodiment is shown in Figures 17-19. Similar to the embodiment shown in Figures 14-16, the embodiment shown in Figures 17-19 also provides better inventory control by using capture members that may be easily detached and interchanged with other capture members to form the type of fixation component desired. However, the embodiment shown in Figures 17-19 also provides independent locking of the joint and each capture member rather than providing the simultaneously locking of the joint and one of the two capture members as discussed with regard to several other embodiments.

As shown in Figures 17-19, a fixation component 300 includes a first capture member 302 and a second capture member 330. Capture members 302 and 330 may be designed to retain one of any of a pin, wire, bar, at least a partial ring, or other fixation element. As shown in Figures 17-19, each capture member is designed to receive a bar. A base 304 of first capture member 302 includes a groove 306, while a head 308 of first capture member 302 contains a wedge 310, which together are adapted to retain a fixation element. Likewise, a base 332 and a head 334 of second

capture member 330 include a groove 336 and a wedge 338, together adapted to retain a fixation element in the same manner as described above.

Head 308 of first capture member 302 has a recess (not shown) adapted to receive a spring 314, while base 304 of first capture member 302 includes a stop 316. 5 The recess, spring 314, and stop 316 function in the same manner as described above. First capture member 302 also includes a first track 318 and a second track 320 so that head 308 and base 304 translate and retain a fixation element in a channel 322 formed by groove 306 and wedge 310 in the same manner as described above. The angular position of channel 322 is set by tightening a first fastener 324. Prior to tightening of 10 first fastener 324, the cartridge mechanism, in the loosened state, does not allow an inserted fixation element to passively separate or detach from capture member 302.

Second capture member 330 also includes a cartridge mechanism for retaining a fixation element. Head 334 of second capture member 330 has a recess 340 adapted to receive a spring 342, while base 332 of second capture member 330 includes a stop 15 344. Second capture member 330 also includes a first track 346 and a second track 348 so that head 334 and base 332 translate and retain a fixation element in a channel 350 formed by groove 336 and wedge 338 in the same manner as described above. The angular position of channel 350 is set by tightening a second fastener 352. Prior to tightening of second fastener 352, the cartridge mechanism, in the loosened state, 20 does not allow an inserted fixation element to passively separate or detach from capture member 330.

In the embodiments shown, the recess, spring, and stop are located on one side of the capture member. In an alternative embodiment, the recess, spring, and spring stop are in the middle of the capture member, or are on the other side of the capture 25 member. In one embodiment, heads 308 and 334 of capture members 302 and 330, respectively, include grip surfaces 326 and 354 for gripping and sliding heads 308 and 334 in relation to bases 304 and 332, respectively. In one embodiment, grip surfaces 326 and 354 include ridges.

A threaded end 356 of second fastener 352 passes through an aperture 358 in 30 head 334 of second capture member 330, mating to internal threads 360 in base 332 of second capture member 330. Tightening of second fastener 352 locks second capture member 330 and rigidly retains an inserted fixation element.

A set screw 370 including threads 372 is inserted into bore 376 in base 304 of first capture member 302. In one embodiment, set screw 370 is tapered. End 374 of set screw 370 is received in a spherical collet 378 of base 304 of first capture member 302. Threads 372 on set screw 370 mate with internal threads 388 of bore 376 of base 5 304 of first capture member 302.

A spherical pocket 390 of base 332 of second capture member 330 receives spherical collet 378. When set screw 370 is tightened, spherical collet 378 expands and the joint between first and second capture members 302 and 330 is rigid. In a loosened state, when set screw 370 is not tightened, spherical collet 378 may be 10 retained within spherical pocket 390, and spherical collet 378 may or may not be biased against spherical pocket 390 to provide resistance for the joint mechanism. Locking of the joint between the two capture members prevents rotation of either capture member about each other, but neither capture member is locked by tightening of set screw 370. When set screw 370 is partially threaded onto internal threads 388 15 of base 304 of first capture member 302 and spherical collet 378 is within spherical pocket 390 but not fully expanded, capture members 302 and 330 may be rotated about each other. Several mechanisms may be used to improve the locking capabilities of the joint, including coatings, elastic materials, or alternate taper shapes as discussed above.

20 First fastener 324 includes a bore 392 and threads 394. First fastener 324 extends through an aperture 380 in head 308 of first capture member 302 and threads 394 are threaded onto internal threads 388 of base 304 of first capture member 302. Tightening of first fastener 324 locks capture member 302. Bore 392 extends through first fastener 324, allowing for insertion of a tool 396 to tighten or loosen set screw 25 370 in spherical collet 378.

One method of using one form of structure according to this invention, shown in Figure 13, is as follows:

At least two half pins are self-drilled into a bone, one on either side of a bone fracture. One bar-to-pin fixation component is connected to each pin by placing each 30 pin into the capture member of each fixation component sized to receive a pin, such as the first capture member of the bar-to-pin fixation component shown in Figure 1. Each fixation element is placed into the fixation component from the side for easy placement. After a pin is in place, the first fastener is tightened, so that the pin is

retained in the capture member, while the second capture member and joint continue to freely rotate. Bars are then snapped into the bar capture member of the fixation components, forming a frame for the system. As each bar is added, the fixation components are adjusted as required by loosening the joint and second capture member, so that optimal positioning may be obtained. Bar-to-bar fixation components and bar-to-pin fixation components may be added to expand and connect the frame as required. If it is necessary or desirable to utilize a circumferential ring or half ring with a system for complex fractures, as shown in Figure 13, additional fixation components having capture members designed to retain the rectangular bar of a ring are used to join the standard system to the specialized frame. A T-component is used to capture the rectangular bar of a ring and link it to a bar of the original frame, forming a hybrid system. If additional reduction is required, one capture member of any component may be loosened without losing placement of the system. A T-component may also be used to provide stability to an existing system that has already been placed using standard fixation component designs. A plurality of clamps may be used in various configurations to achieve stability for different fractures.

Similar instrumentation and devices may be used in other areas, such as to provide a fixed reference to a pin. Constructs made under the present invention are stable and provide for a wide variety of placements. Embodiments of an external fixation component according to this invention may also be adapted for use with an image guided surgery system to provide stability to a reference frame or other guidance target or mechanism.

The foregoing description of certain exemplary embodiments of the invention has been presented only for the purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations are possible in light of the above teaching.

The embodiments were chosen and described in order to explain the principles of the invention and their practical application so as to enable others skilled in the art to utilize the invention and various embodiments and with various modifications as are suited to the particular use contemplated. Alternative embodiments will become apparent to those skilled in the art to which the present invention pertains without departing from its spirit and scope. Accordingly, the scope of the present invention is

defined by the appended claims rather than the foregoing description and certain exemplary embodiments described therein.

Claims

1. An external fixation component comprising:

(a) a first capture member adapted to capture a first element of an orthopedic fixation system; and

(b) a second capture member adapted to capture a second element of an orthopedic fixation system and coupled to the first capture member such that the coupling allows the first capture member and the second capture member to rotate about three axes relative to each other and the second capture member to rotate about one axis of the second element and move along that axis;

wherein the coupling is adapted to secure the first and second capture members from rotation with an activation; and

wherein the second capture member is adapted to capture the second element by snapping onto the second element from substantially perpendicular to the longitudinal axis of the second element.

2. A component according to claim 1, wherein the activation also secures the second member from rotating about and moving along the axis of the second element.

3. A component according to claims 1 or 2, wherein the first capture member is adapted to capture the first fixation element by snapping onto the first fixation element from substantially perpendicular to the longitudinal axis of the first fixation element.

4. A component according to any of claims 1-3, wherein the coupling comprises at least one ball and socket joint and the activation applies tension to a connector that links the first and second capture members.

5. A component according to claim 4, wherein the coupling is adapted to apply tension to the connector in an adjustable fashion.

6. A component according to claim 4, wherein the ball and socket joints share substantially the same center of rotation.

7. A component according to any of claims 1-3, wherein one capture member may be locked while the other capture member is capable of rotation.

8. A component according to any of claims 1-3, wherein each capture member further comprises a base and a head movably coupled to the base, wherein the movement of the head occurs substantially in a plane such that when the head is moved to a first position a fixation element may be placed in a location to be captured between the base and the head, and when the head is moved to a second position the fixation element is captured between the base and the head.

9. A component according to claim 8, wherein at least a portion of the movement between the head and the base is sliding movement.

10. A component according to claim 8, wherein the head is biased toward the second position.

11. A component according to claim 8, wherein the head of each of the capture members further comprises a wedge and the base of each of the capture members further comprises a groove.

12. A component according to claim 11, wherein the wedge and groove of each capture member form a channel adapted to receive a fixation element.

13. A component according to claim 8, further comprising:  
a connector;  
internal threads in an aperture of the base of the first capture member, wherein the aperture is adapted to receive a first fastener;  
a first fastener comprising a threaded end adapted to mate with the internal threads of the base;  
a biasing member adjacent an end of the connector and wherein the threaded end of the first fastener is adjacent the biasing member; and

threads on a second portion of the connector adapted to mate with threads on a second fastener.

14. A component according to claim 13, wherein tightening the first fastener locks the first capture member and tightening the second fastener locks the second capture member.

15. A component according to any of claims 1-3, wherein each capture member is adapted to receive a bar, a pin, a wire, or at least a partial ring.

16. A component according to any of claim 1-3, wherein one capture member is adapted to receive a bar and the other capture member is adapted to receive a wire, a pin, or at least a partial ring.

17. A component according to any of claims 1-3, wherein:  
the first capture member comprises a planetary member having inner and outer surfaces and includes an aperture adapted to receive a connector; and  
the second capture member comprises a cooperating surface adapted to receive and correspond generally in shape with the outer surface of the planetary member and includes an aperture adapted to receive a connector.

18. A component according to claim 17, further comprising a connector including a first portion that corresponds generally in shape to and is adapted to be received in the inner surface of the planetary member, and a second portion adapted to extend through the aperture in the cooperating surface of the second capture member;

wherein when the first portion of the connector is urged against the inner surface of the planetary member and locked, and the outer surface of the planetary member is urged against the cooperating surface and locked, the fixation components are oriented and locked in position relative to each other, and

wherein when unlocked, each capture member is able to rotate about more than one axis relative to the other capture member.

19. A component according to claim 18, wherein the first portion of the connector comprises a generally spherical end and the second portion of the connector comprises a shaft.

20. A component according to claim 18, wherein the connector further comprises a key adapted to be received in a slot in the second capture member.

21. A component according to claim 18, further comprising a biasing member adjacent the first portion of the connector.

22. A component according to claim 18, wherein the planetary member and cooperating surface are generally spherical.

23. A component according to claim 18, wherein the inner surface of the planetary member and the cooperating surface are tapered.

24. A component according to claim 18, wherein the planetary member and the cooperating surface are textured.

25. An external fixation system comprising a component according to any of claims 1-3 and a plurality of fixation elements.

26. A system according to claim 25, wherein the fixation elements comprise at least one bar, at least one pin, at least one wire, or at least one at least partial ring.

27. An external fixation device comprising a component according to any of claims 1-3.

28. A method of treating a skeletal condition or injury using an external fixation system, the method comprising:

- (a) inserting a first fixation element into a bone;

(b) capturing the first fixation element in a first fixation component by snapping onto the first fixation element from substantially perpendicular to the longitudinal axis of the first fixation element, the first fixation component comprising:

(i) a first capture member adapted to capture an element of an orthopedic fixation system; and

(ii) a second capture member adapted to capture an element of an orthopedic fixation system and coupled to the first capture member such that the coupling allows the first capture member and the second capture member to rotate about three axes relative to each other;

wherein the coupling is adapted to secure the first and second capture members from rotation with a single activation;

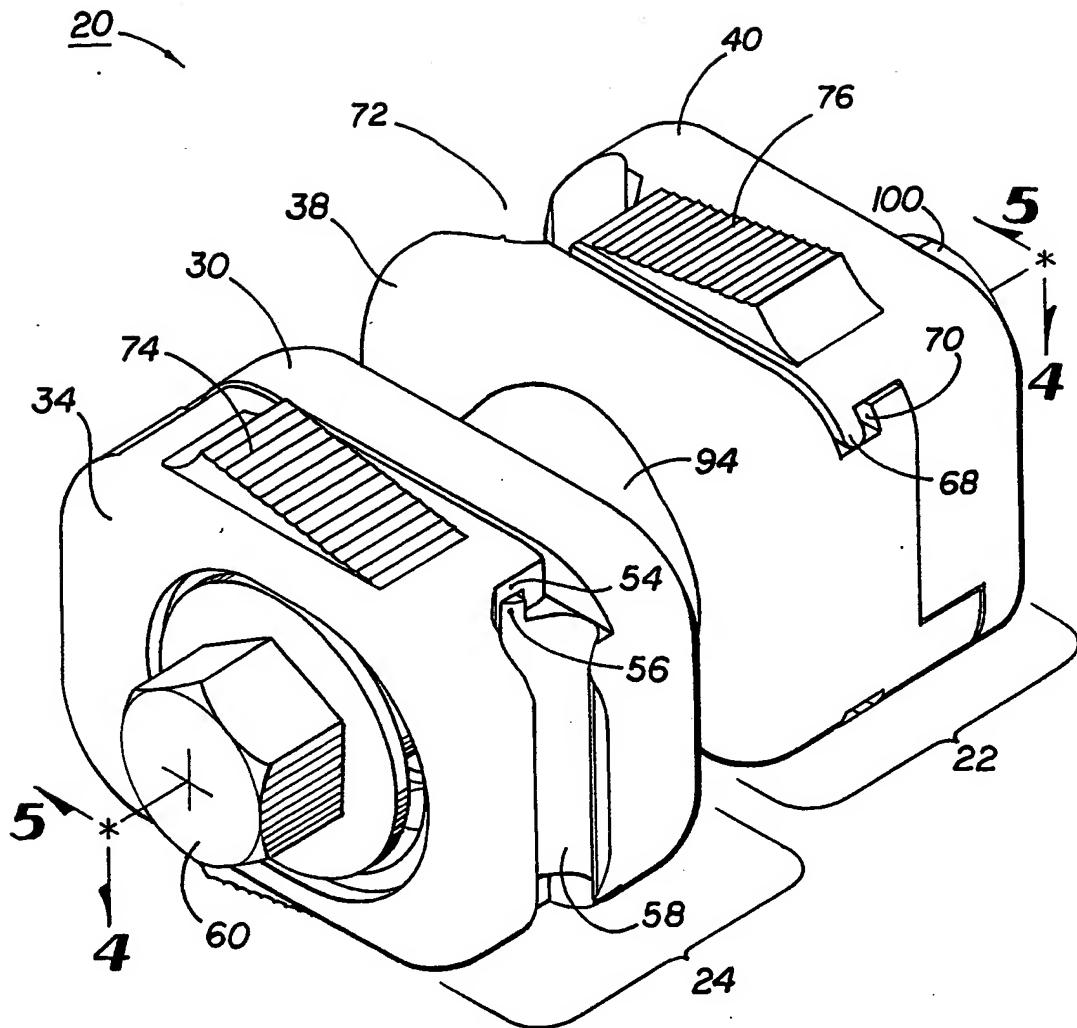
(c) capturing a second fixation element in the first fixation component by snapping onto the second fixation element from substantially perpendicular to the longitudinal axis of the second fixation element; and

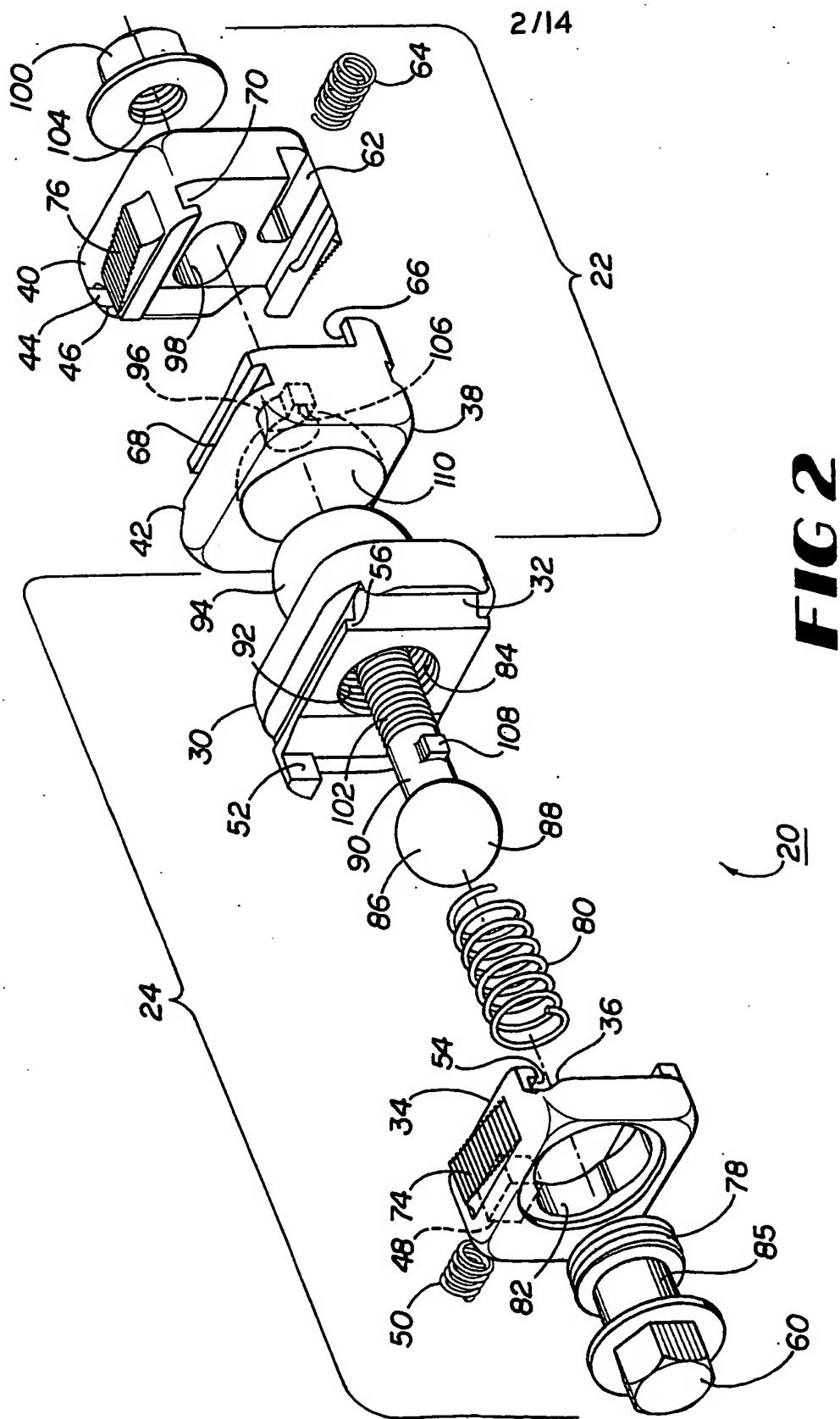
(d) engaging the single activation to secure the first and second capture members from rotation.

29. The method of claim 28, further comprising joining one of the first fixation element or the second fixation element to a second component, forming a frame.

30. The method of claim 29, further comprising adjusting the frame by loosening one capture member of any fixation component and moving the frame.

1/14

**FIG A**



3/14

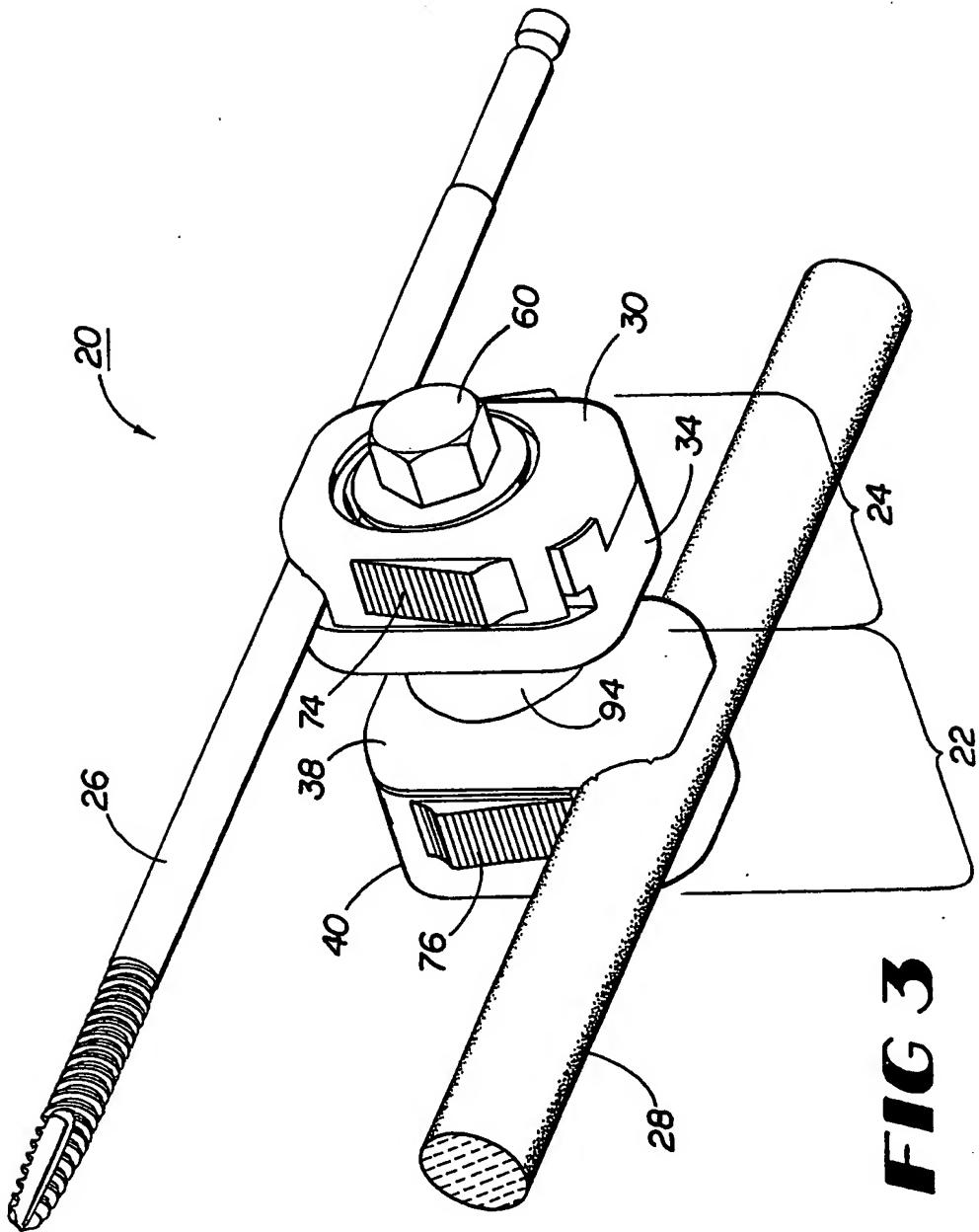
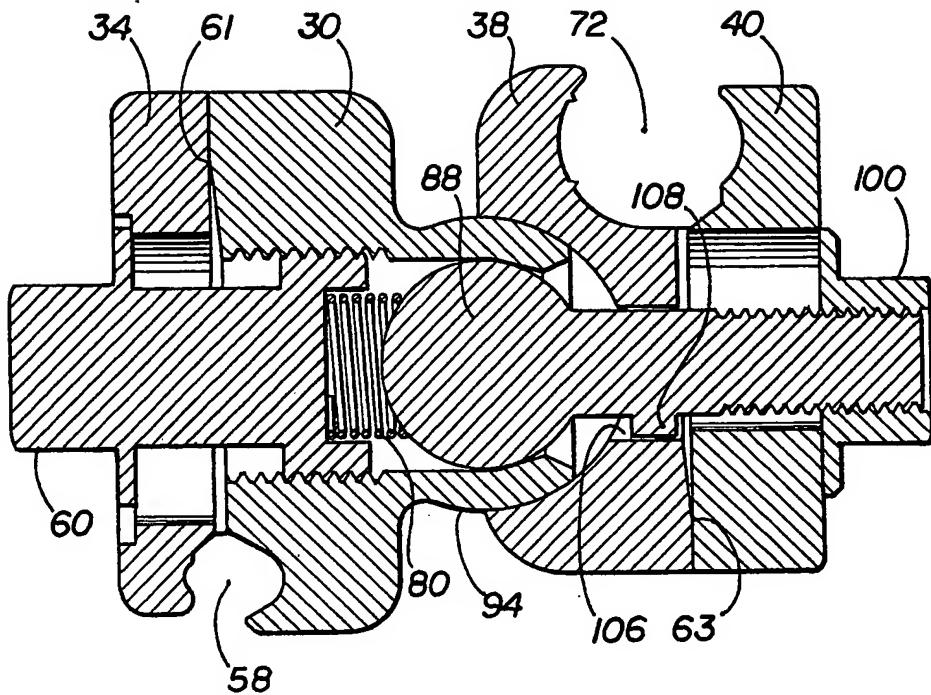
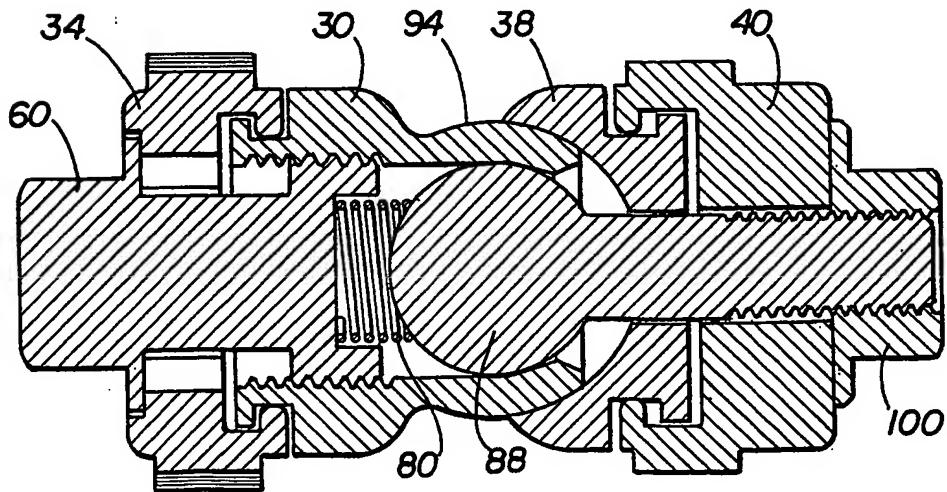
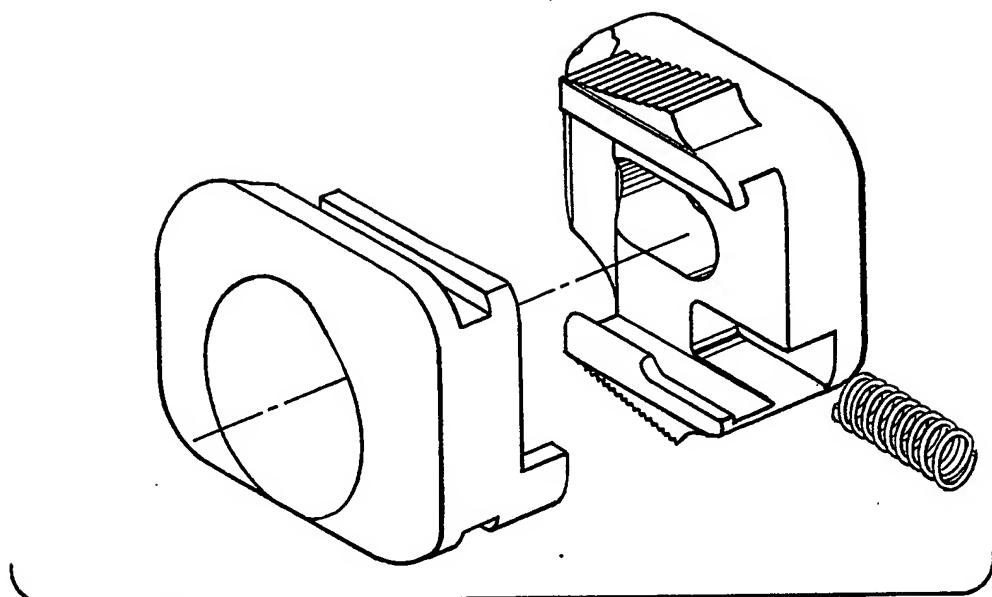
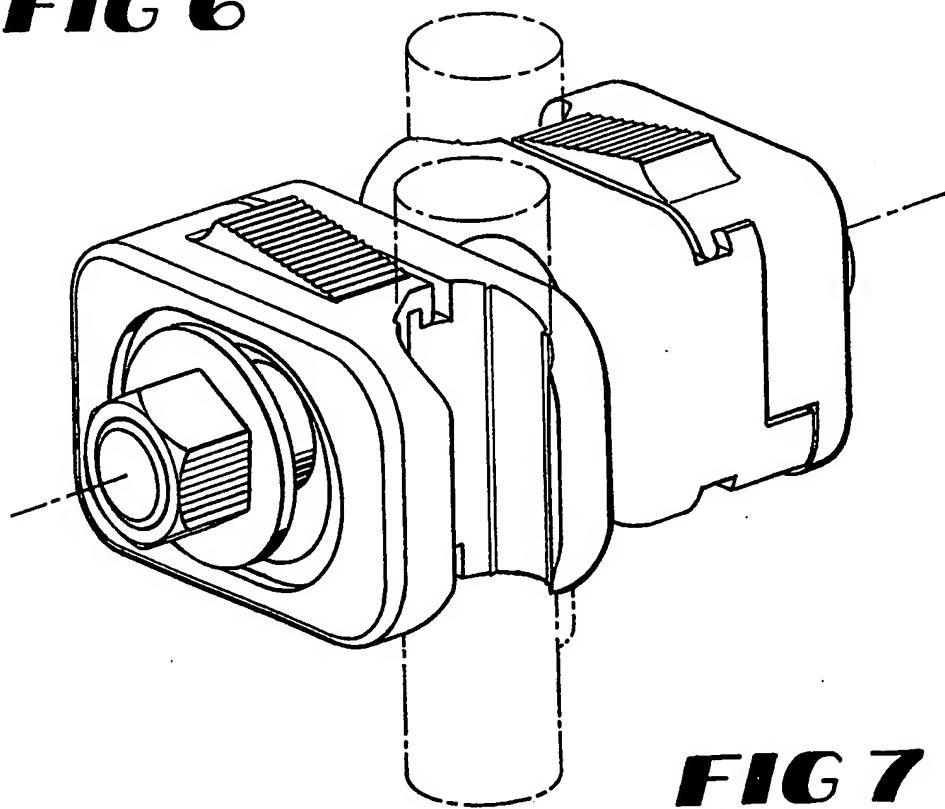


FIG 3

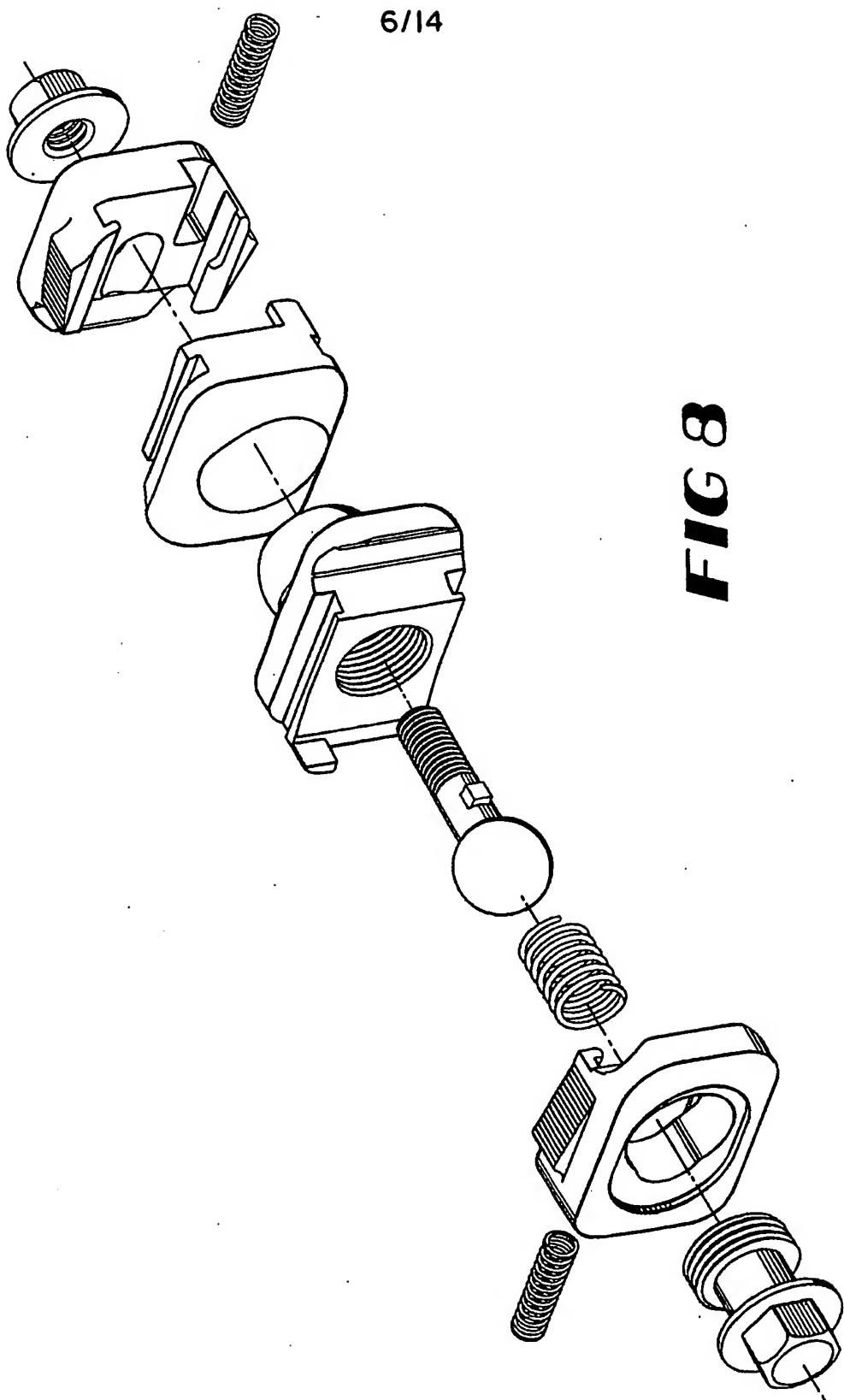
4/14

**FIG 4****FIG 5**

5/14

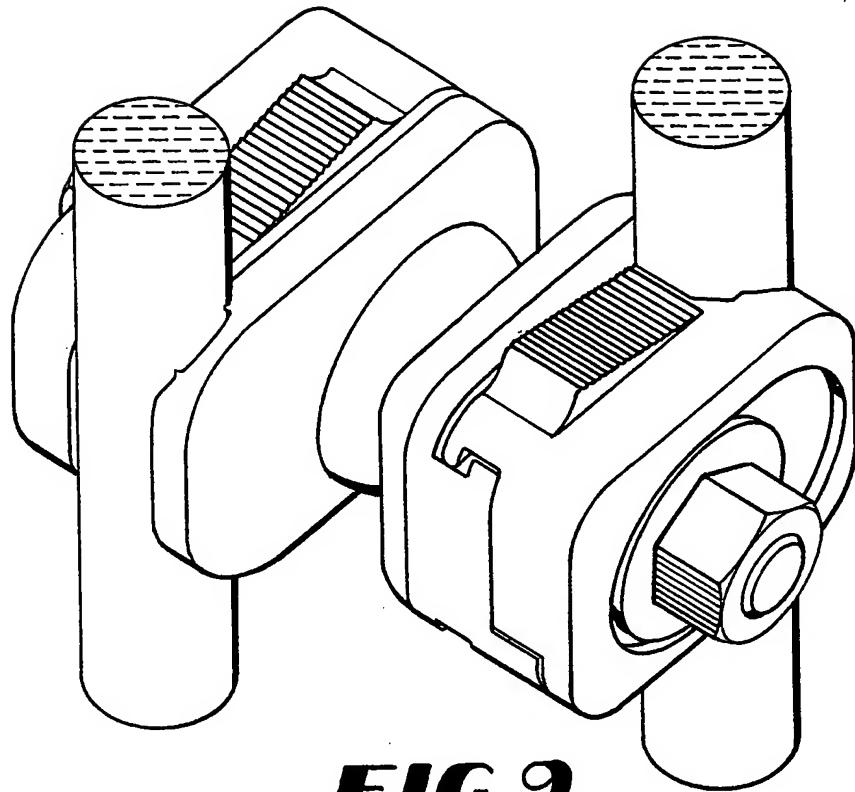
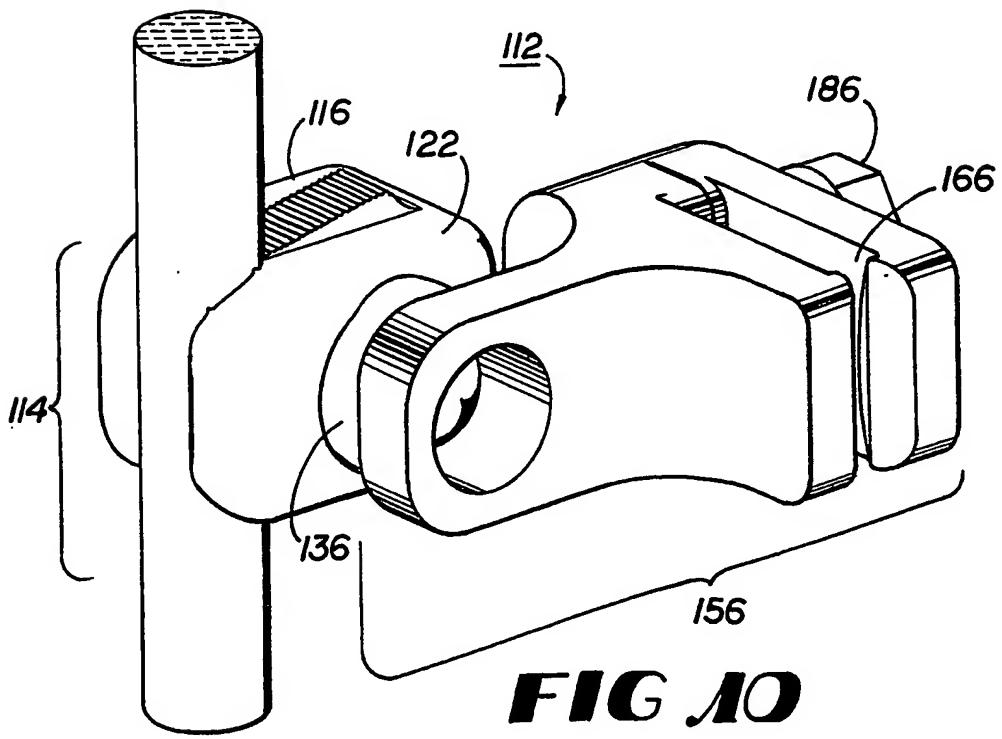
**FIG 6****FIG 7**

6/14

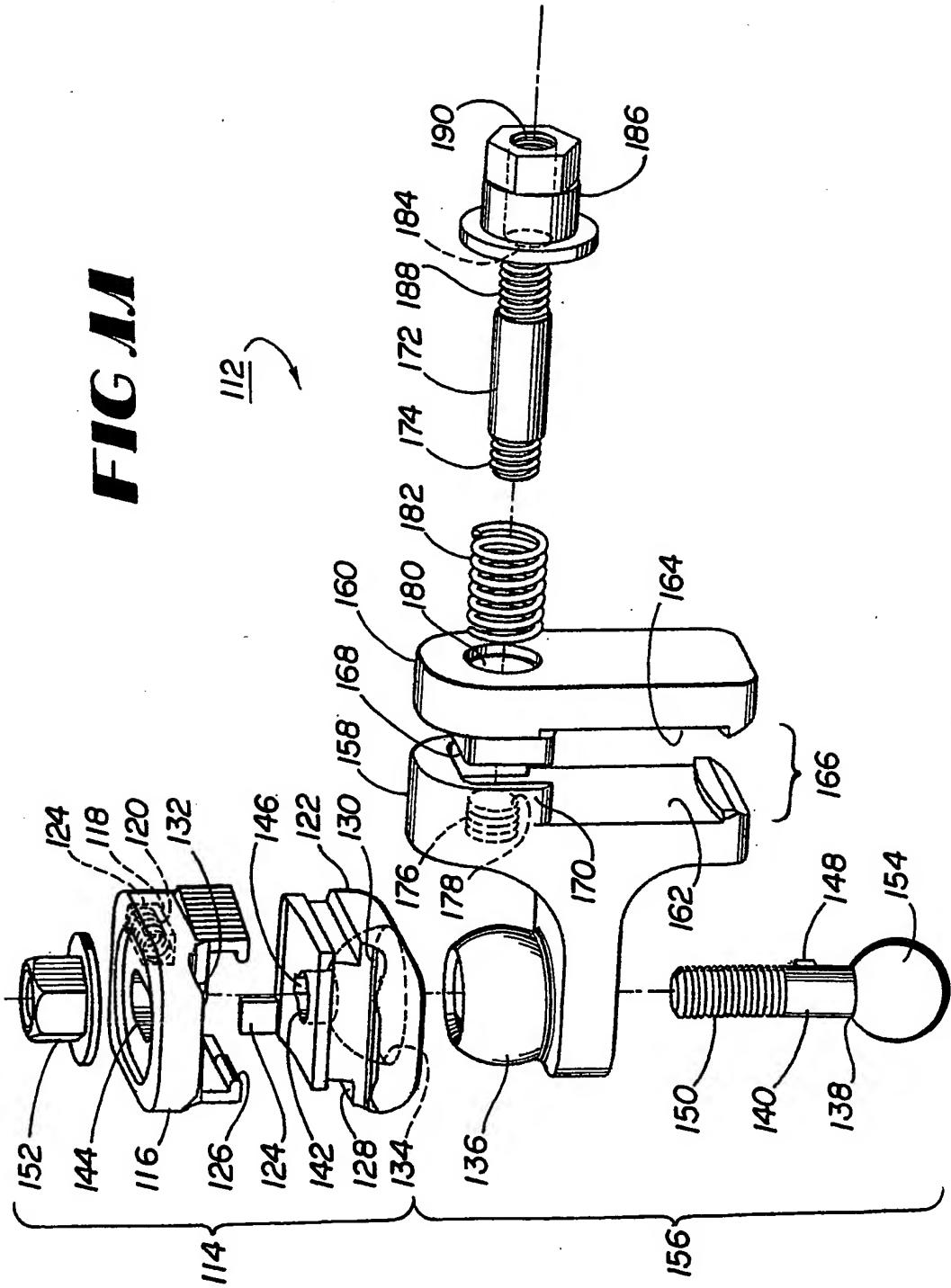


**FIG 8**

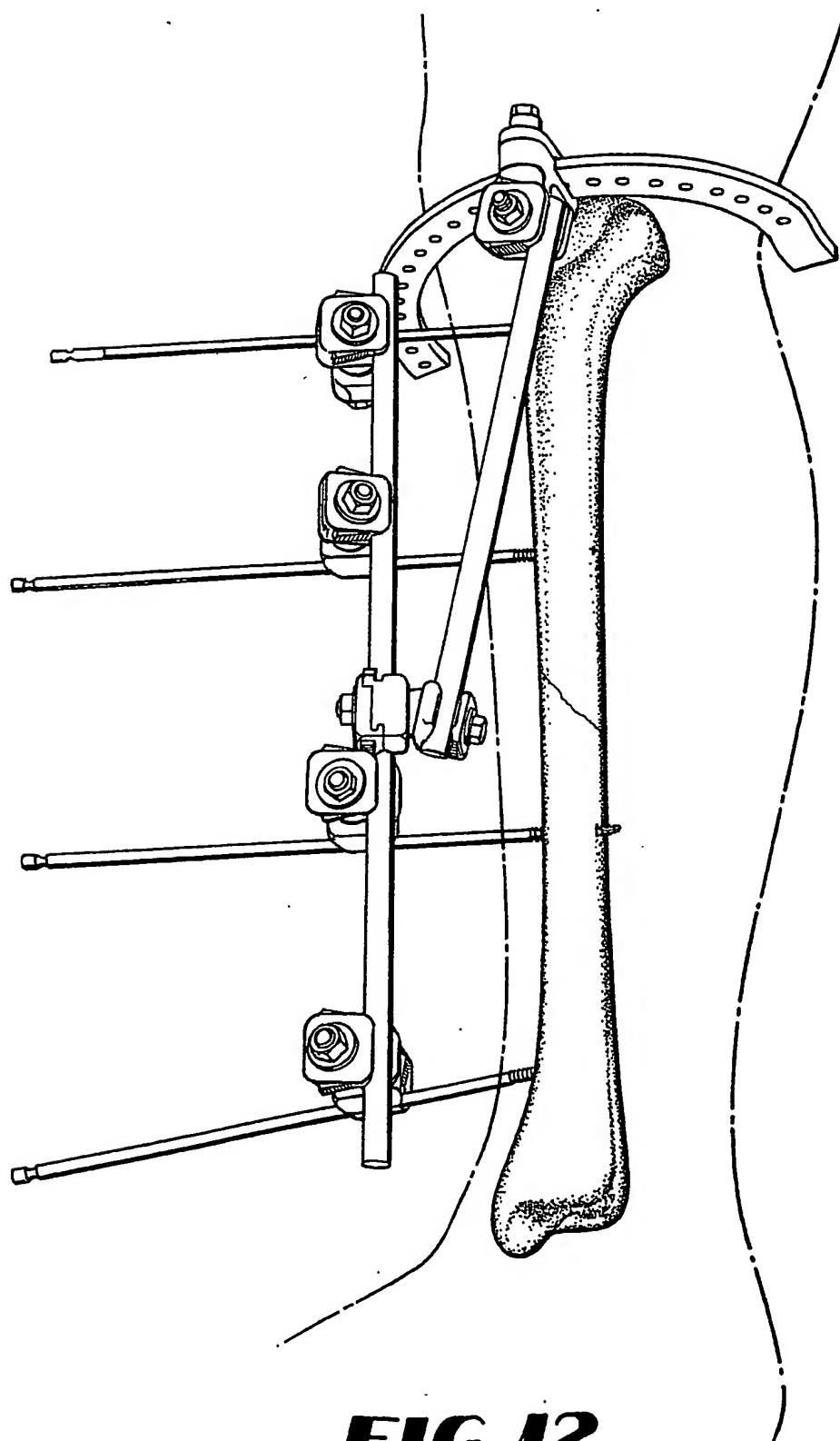
7/14

**FIG 9****FIG 10**

8/14

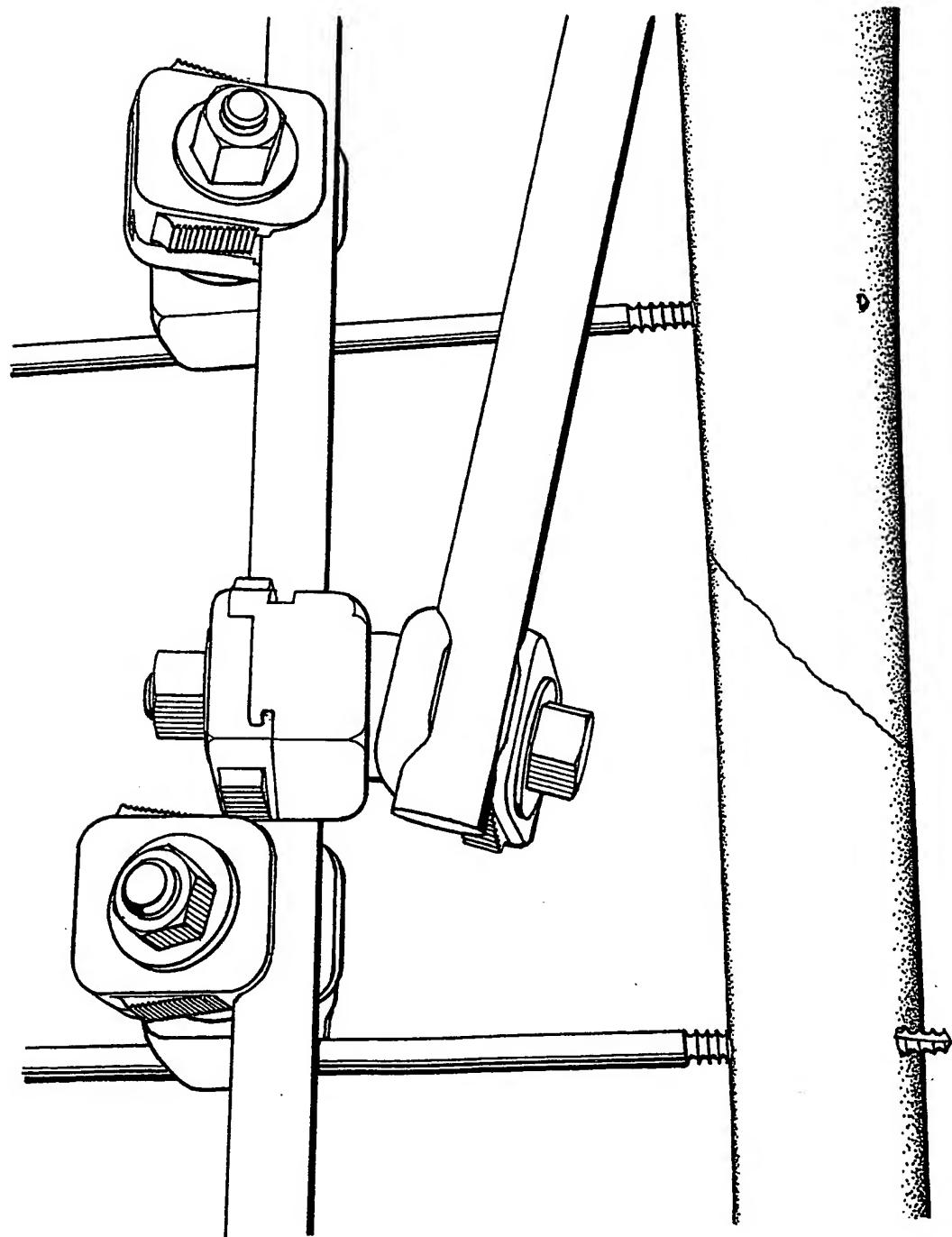


9/14

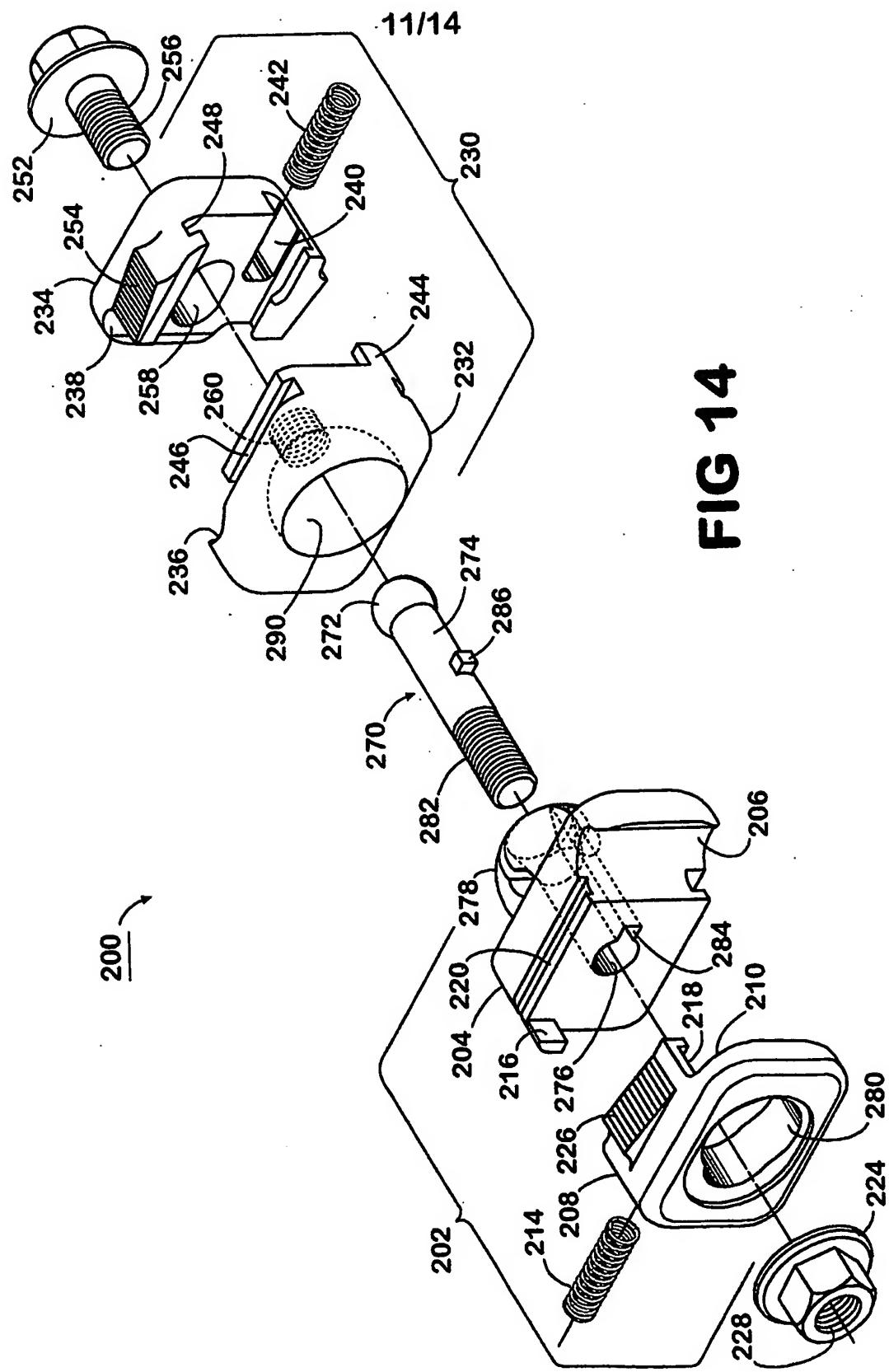


**FIG A2**

10/14



**FIG 13**

**FIG 14**

12/14

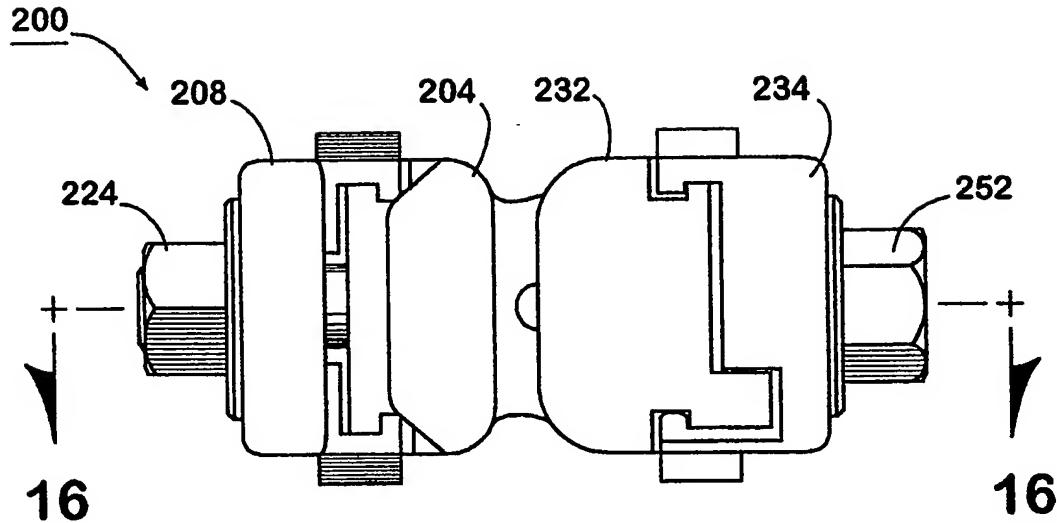


FIG 15

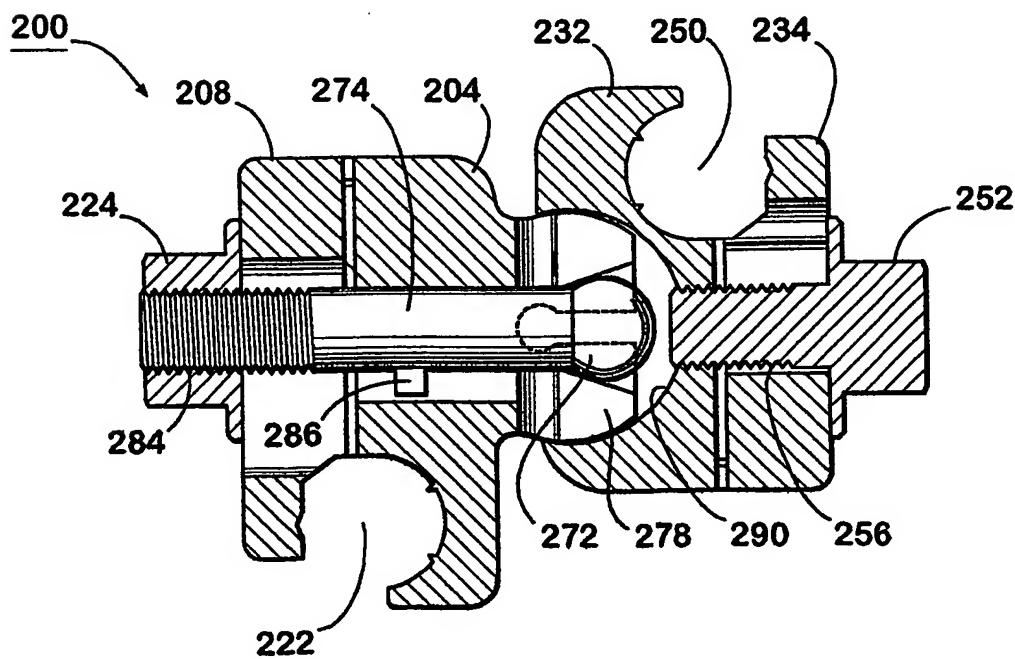
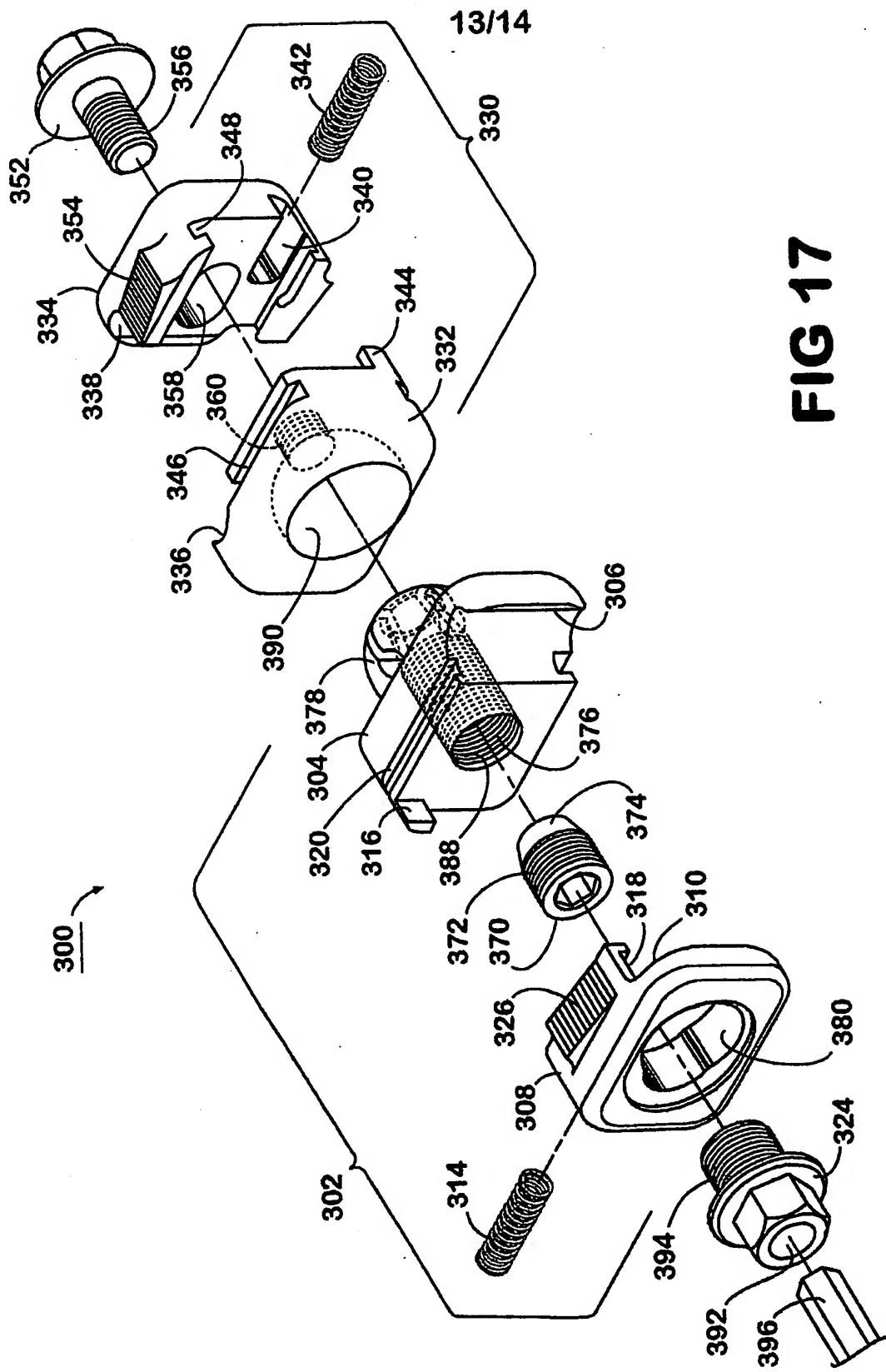


FIG 16



14/14

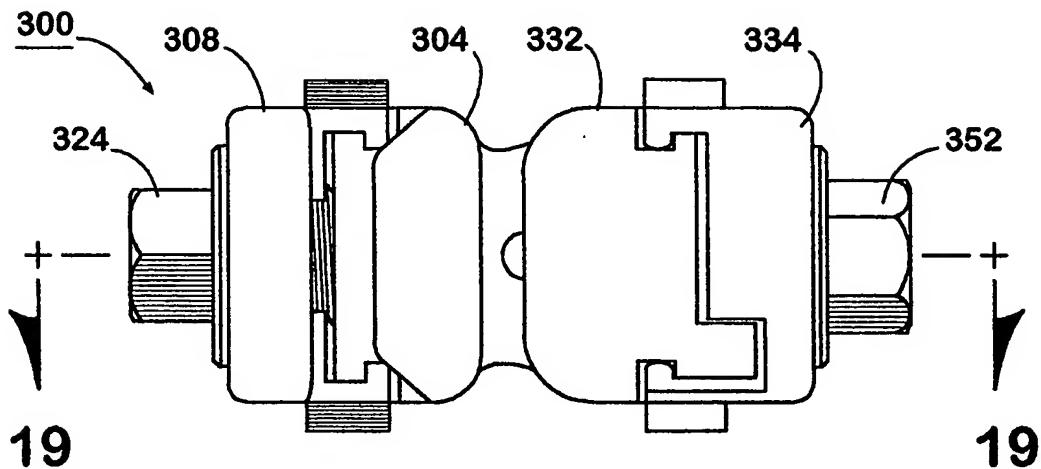


FIG 18

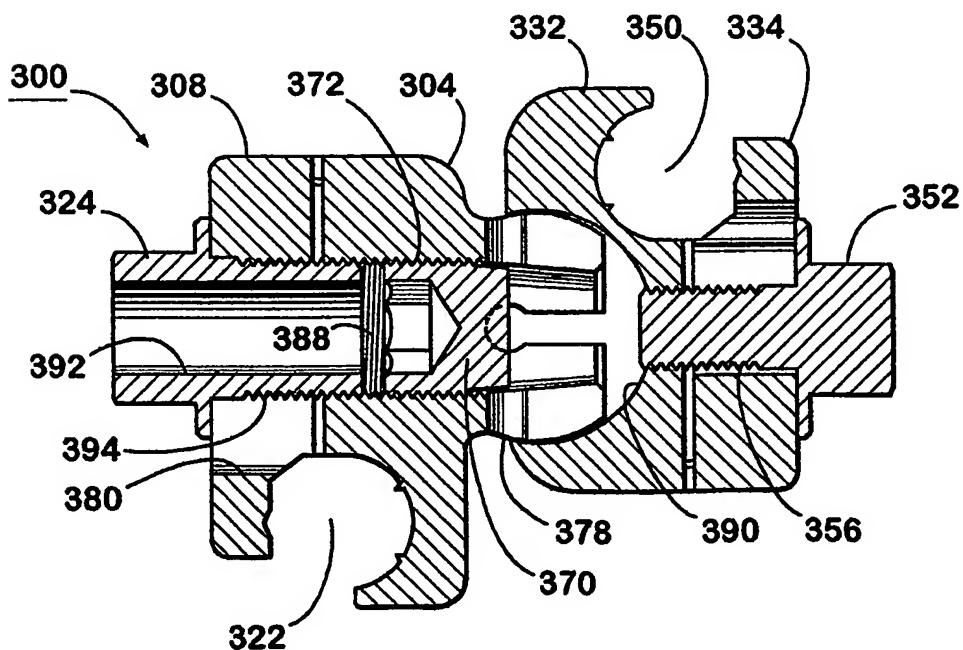


FIG 19

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US 03/02712A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/64

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 144 A (J.MATA ET AL.) 6 April 1999 (1999-04-06) abstract column 1, line 18 - line 30 column 1, line 40 - line 42 column 2, line 36 - line 47 figures 2,3	1-16
Y	US 5 752 954 A (J.MATA ET AL.) 19 May 1998 (1998-05-19) abstract; figures 1,4	1-16
Y	EP 1 021 992 A (MEDICALPLASTIC) 26 July 2000 (2000-07-26) figures 1,2	1-16
		-/-

 Further documents are listed in continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the International filing date but later than the priority date claimed

- "T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "8" document member of the same patent family

Date of the actual completion of the International search

2 June 2003

Date of mailing of the International search report

10/06/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl  
 Fax: (+31-70) 340-3018

Authorized officer

Nice, P

## INTERNATIONAL SEARCH REPORT

International	Location No.
PCT/US 03/02712	

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CH 303 453 A (R HOFFMANN) 30 November 1954 (1954-11-30) page 1, line 38 -page 2, line 18; figures	1

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 03/02712

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 28-30 because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery**
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- The additional search fees were accompanied by the applicant's protest  
 No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Publication No	
PCT/US	03/02712

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 5891144	A 06-04-1999		CH 691568 A5 AU 2016697 A CA 2204449 A1 EP 0806185 A1 JP 3085919 B2 JP 10057397 A AT 228337 T AU 718087 B2 DE 69717343 D1 DE 69717343 T2 ES 2185892 T3	31-08-2001 13-11-1997 10-11-1997 12-11-1997 11-09-2000 03-03-1998 15-12-2002 06-04-2000 09-01-2003 27-03-2003 01-05-2003
US 5752954	A 19-05-1998		CH 690293 A5 US 6080153 A AT 185057 T AU 686852 B2 AU 3043795 A CA 2157536 A1 DE 29512917 U1 DE 69512489 D1 DE 69512489 T2 EP 0700664 A1 ES 2138714 T3 JP 2609442 B2 JP 8071084 A KR 166622 B1	14-07-2000 27-06-2000 15-10-1999 12-02-1998 21-03-1996 07-03-1996 19-10-1995 04-11-1999 18-05-2000 13-03-1996 16-01-2000 14-05-1997 19-03-1996 15-01-1999
EP 1021992	A 26-07-2000		IT MI990100 A1 EP 1021992 A2 US 6217577 B1	21-07-2000 26-07-2000 17-04-2001
CH 303453	A 30-11-1954		NONE	